

REMARKS

Claims 31-78 are pending in the application. Claims 75-78 are withdrawn.

Reconsideration of the present application is respectfully requested.

Rejection under 35 USC Section 103

The Examiner has maintained the rejection of claims 31-74 as being obvious over Romanczyk, Jr. (US 5,554,645; hereinafter referred to as 'Romanczyk') in view of Wideman *et al.* (US 6,127,421; hereinafter referred to as 'Wideman'). Reconsideration is respectfully requested in view of the following remarks.

The Examiner states that "it would have been obvious [to combine the Romanczyk food composition and Wideman's L-arginine] because the two above combined teachings would create the claimed food compositions used for anti-tumor purposes" (Official Action, page 3). However, whether two compounds/compositions of prior art would have created the claimed compositions is not the proper legal standard of obviousness. The legal standard of obviousness requires both (i) some reason (motivation) to combine the prior art compounds/compositions, and (ii) a reasonable expectation that such a combination would have been successful; plus, the prior art must suggest all claimed limitations. MPEP Section 2143.

With respect to the requirement (i) above, the Examiner states that a person of skill in the art would have been motivated to combine compounds/compositions of Romanczyk and Wideman because both are taught to be useful for the same purpose. However, "prior art must be considered in its entirety, including disclosures that teach away from the claims" MPEP, Section 2141.02 VI. "When prior art contains apparently conflicting references, the [Office] must weigh each reference for its power to suggest solutions to an artisan of ordinary skill." *In re Young*, 927 F.2d 588, 591; 18 U.S.P.Q.2d 1089 (Fed. Cir. 1991).

Applying this principle here, a person of skill in the art would have considered not only Wideman (as the Office here implies) but also Yeatman T. J. *et al.* Depletion of Dietary Arginine Inhibits Growth of Metastatic Tumor, *Arch. Surg.* 1991, 126(11):1376-82 (copy of record with the Office), which showed results contradictory to those of Wideman, *i.e.*, Yeatman showed that dietary arginine depletion inhibited the growth of liver metastases of colorectal cancer cells. Therefore a person of skill in the art would not have been motivated to modify the food of Romanczyk by adding L-arginine because the actual effects of L-arginine on tumor were not known. The legal requirement that both compounds/compositions were known for the same purpose is not met.

Moreover, even if motivation existed, regarding the requirement (ii) above, the reasonable expectation of success, the Examiner provides no explanation or reasoning as to why that requirement is satisfied. In fact, because certain prior art suggested that reducing (rather than adding) L-arginine would have been beneficial for tumors, a person of skill in the art would not have had any reasonable expectation of success that the combined composition would have been beneficial. Experimentation would have been required, which supports the finding of non-obviousness.

Further referring to MPEP Section 2143, the prior art must suggest all claimed limitations. The Examiner states that the claimed amount ("to induce a physiological increase in nitric oxide") is "merely a matter of judicious selection and routine optimization" (Official Action, text spanning pages 3-4). However, only result-effective variables can be optimized. MPEP Section 2144.05 II B. "A particular parameter must first be recognized as a result-effective variable, *i.e.*, a variable which achieves a recognized result, before the determination of the optimum or workable ranges of said variable might be characterized as routine experimentation." *Id.* This is not the case here because the cited prior art fails to teach that the compounds cited in Applicant's claims have nitric oxide effect; hence, in the absence of such a recognized result, arriving at the above quoted structural limitation of Applicants claims would not have amounted to routine optimization.

In view of the above remarks, withdrawal of the rejection is believed to be in order. An action to that effect is respectfully requested.

CONCLUSION

In view of the above remarks, Applicants believe that the application is now in condition for allowance. A notice to that effect is respectfully requested.

Date: October 8, 2007

Respectfully submitted,



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